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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,872	04/05/2001	Alan Solomon	044137-5029-US	3133

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EXAMINER
CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/825,872	Applicant(s) SOLOMON ET AL.	
	Examiner Deborah Crouch	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to methods of removing amyloid fibrils in a patient comprising administering amyloid fibril and a vaccine comprising amyloid fibril, classified in class 514, subclass 12.

II. Claims 4-27, 31 and 32, drawn to a transgenic nonhuman animal, methods of increasing the rate of development of amyloid deposits in a transgenic nonhuman animal and methods of identifying an agent effective in preventing amyloidosis, classified in class 800, subclass 13.

III. Claim 28, drawn to a method of detecting an agent that inhibits fibrillogenesis comprising incubating a test agent with a protein known to be fibrillogenic, classified in class 435, subclass 23.

IV. Claim 28, drawn to a method of determining a compound that is fibrillogenic comprising incubating a compound with ThT, classified in class 435, subclass 23.

V. Claim 30, drawn to a method for identifying the nature of proteins in amyloid deposits comprising determining the amino acid sequence of the proteins, classified in class 436, subclass 86.

The inventions are distinct, each from the other because:

Inventions I and II are mutually exclusive and independent methods. Invention I is to an in vivo method of treatment. Invention II is to an in vivo method of identifying an agent effective in treating amyloidosis using a transgenic animal. The protocols for the method of treatment of invention I are materially different and separate from the protocols for the method of identifying of invention II. In addition,

the method of treatment of invention I is not required for the method of identifying of invention II, and vice-versa.

Inventions I and III are mutually exclusive and independent methods. Invention I is to an in vivo method of treatment. Invention III is to an in vitro method of identifying an agent that inhibits fibrillogenesis. The protocols for the method of treatment of invention I are materially different and separate from the protocols for the method of identifying of invention III. In addition, the method of treatment of invention I is not required for the method of identifying of invention III, and vice-versa.

Inventions I and IV are mutually exclusive and independent methods. Invention I is to an in vivo method of treatment. Invention IV is to an in vitro method of determining if an agent is fibrillogenic. The protocols for the method of treatment of invention I are materially different and separate from the protocols for the method of determining of invention IV. In addition, the method of treatment of invention I is not required for the method of determining of invention IV, and vice-versa.

Inventions I and V are mutually exclusive and independent methods. Invention I is to an in vivo method of treatment. Invention V is to an in vitro method of identifying the nature of proteins in an amyloid deposit by amino acid sequencing. The protocols for the method of treatment of invention I are materially different and separate from the protocols for the method of identifying of invention V. In addition, the method of treatment of invention I is not required for the method of identifying of invention V, and vice-versa.

Inventions II and III are mutually exclusive and independent methods. Invention II is to an in vivo method of identifying an agent effective in treating

amyloidosis using a transgenic animal. Invention III is to an in vitro method of identifying an agent that inhibits fibrillogenesis. The protocols for the method of identifying an agent of invention II are materially different and separate from the protocols for the method of identifying and agent of invention III. In addition, the method of identifying of invention II is not required for the method of identifying of invention III, and vice-versa.

Inventions II and IV are mutually exclusive and independent methods. Invention II is to an in vivo method of identifying an agent effective in treating amyloidosis using a transgenic animal. Invention IV is to an in vitro method of determining if an agent is fibrillogenic. The protocols for the method of identifying an agent of invention II are materially different and separate from the protocols for the method of identifying an agent of invention IV. In addition, the method of identifying of invention II is not required for the method of identifying of invention IV, and vice-versa.

Inventions II and V are mutually exclusive and independent methods. Invention II is to an in vivo method of identifying an agent effective in treating amyloidosis using a transgenic animal. Invention V is to an in vitro method of identifying the nature of proteins in amyloid deposits by amino acid sequencing. The protocols for the method of identifying an agent of invention II are materially different and separate from the protocols for the method of identifying the nature of invention V. In addition, the method of identifying of invention II is not required for the method of identifying of invention V, and vice-versa.

Inventions III and IV are mutually exclusive and independent methods. Invention III is to an in vitro method of identifying an agent that inhibits fibrillogenesis. Invention IV is to an in vitro method of determining if an agent is

fibrillogenic. The protocols for identifying an inhibitor of invention III and the protocols for determining if an agent is fibrillogenic are materially different and separate. In addition, the methods of identifying of invention III is not required for the method of determining of invention IV, and vice-versa.

Inventions III and V are mutually exclusive and independent methods. Invention III is to an in vitro method of identifying an agent that inhibits fibrillogenesis. Invention V is to an in vitro method of identifying the nature of proteins in amyloid deposits by amino acid sequencing. The protocols for the method of identifying an agent of invention III are materially different and separate from the protocols for the method of identifying the nature of invention V. In addition, the method of identifying of invention III is not required for the method of identifying of invention V, and vice-versa.

Inventions IV and V are mutually exclusive and independent methods. Invention IV is to an in vitro method of determining if an agent is fibrillogenic. Invention V is to an in vitro method of identifying the nature of proteins in amyloid deposits by amino acid sequencing. The protocols for the method of determining of invention IV are materially different and separate from the protocols for the method of identifying the nature of invention V. In addition, the method of determining of invention IV is not required for the method of identifying of invention V, and vice-versa.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for any of Groups I-V is not co-extensive, restriction for examination purposes as indicated is proper.

A telephone call was made to Ms. Sally Teng on April 19, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
April 23, 2002